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THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP
100 GALLERIA PARKWAY, NW
STE 1750
ATLANTA, GA 30339-5948

EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

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DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,998

Applicant(s)

ARMSTRONG, DAVID N.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 April 2002.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
4a) Of the above claim(s) 1-25 and 36-54 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 April 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a ligation system with a ligator, shaft, handle, head assembly, and anoscope, classified in class 606 subclass 140.
- II. Claims 26-35, drawn to a system with an anoscope, ligator, and a loading cone, classified in class 606, subclass 141.
- III. Claims 36-47, drawn to a method for ligating hemorrhoids, classified in class 606, subclass 138.
- IV. Claims 48-54, drawn to a ligator having a head, inner cylinder, and shaft, classified in class 606, subclass 140.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as ligating part of the stomach. Moreover inventions I and II are drawn to two structurally different systems with different components. See MPEP § 806.05(d).

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

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another and materially different process. (MPEP § 806.05(e)). In the instant case, group I has separate utility such as ligating part of the stomach.

Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination requires the ligator to have a head assembly including an inner cylinder. The subcombination has separate utility such as the ligation of the intestines or stomach.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In the instant case, group II has separate utility such as ligating part of the stomach.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination requires the ligator to have a head assembly including an

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inner cylinder. The subcombination has separate utility such as the ligation of the intestines or stomach.

Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In the instant case, group III has separate utility such as ligating part of the stomach.

Because these inventions are distinct for the reasons given above and the search required for Groups I-V are different, restriction for examination purposes as indicated is proper.

During a telephone conversation with George Thomas on April 1, 2004 a provisional election was made without traverse to prosecute the invention of group II, claims 26-35.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-25, and 36-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

1. The claims are objected to because they include reference characters which are not enclosed within parentheses. Only claim 32 has this deficiency. Either place the number in parentheses or delete it from the claim.

Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in

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the claims should be enclosed within parentheses so as to avoid confusion with other numbers or characters which may appear in the claims. See MPEP § 608.01(m).

Specification

2. The disclosure is objected to because of the following informalities: figure 5 is not discussed in the specification. It should not be included if it is not discussed in the specification

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the springs of the ratchet device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The drawing points to empty space where some sort of spring should be.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Looking at figure 7 and claim 34, a system of springs is recited that works in conjunction with a ratcheting mechanism. The actual construction of this system is not disclosed in the drawings since the shape and locations of the springs is omitted. From the disclosure, one of ordinary skill in the art would not be able to build or use the device as shown in figure 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 26-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson Jr et al. (Watson) 5788715 in view of Bidoia 5203863 and in further view of Longo et al. (Longo) 6142933. The Watson device discloses a system for ligation of internal hemorrhoids comprising a ligator device configured to store multiple bands on a cylinder and further configured to release a single rubber band at a time from the cylinder. No anoscope or loading cone is disclosed by Watson. Longo discloses an anoscope having multiple apertures (106 has four apertures). To perform a hemorrhoid surgery it is well known in the art to use an anoscope to allow the ligation tool to enter the anus. Longo illustrates this by showing the stapler that is intended to be put through his anoscope. Additionally, the applicant discloses in figure 2 an anoscope that is prior art. At the time of the invention it would have been obvious to one having

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ordinary skill in the art to combine the Watson device with the applicant's prior art anoscope because because Longo teaches that hemorrhoid surgery is performed by using a ligating instrument and an anoscope. The combined device does not disclose a reloading mechanism for placing rubber bands onto the Watson device in the event additional bands are needed, or if the surgery is repeated. Bidoia discloses a loading mechanism that allows multiple rubber bands to be placed on the inner cylinder of the Watson device. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Bidoia loading cone to load the Watson ligator so bands to be replaced onto the device.

6. Regarding claim 27, the combined device has three apertures in the anoscope that correspond to normal hemorrhoid locations, the apertures extend laterally in a longitudinal direction half-way along a length of the anoscope, and said apertures having a width approximately equivalent to $1/6$ of a circumference of the anoscope.

7. Regarding claims 28 and 28, the Watson ligator anticipates all the limitations of these claims. The examiner has attached a sheet labeling all of the corresponding parts. Inner cylinder is element 1, outer cylinder 2, central rod 3, outer rod 4, and handle 5.

8. Regarding claim 30, the Watson device is structurally capable of having the inner cylinder removed to allow the reloading of multiple rubber bands.

9. Regarding claim 31, as disclosed the Watson device is structurally capable of having its inner cylinder removed and a new preloaded one placed in the old inner cylinder's place.

10. Regarding claim 32, the disposable cylinder is labeled on the attached figure as element 6. The shoulder is the element that pushes the band off of the cylinder (7).

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11. Regarding claim 35, the modified loading cone is configured with a tapered front section (35) and shouldered recess (31).

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Watson device as applied to claim 29 and in view of Lindquist 3997085. The Watson device uses a very simple handle to affect the necessary force on the inner cylinder to discharge the ligation bands. There are a myriad of different types of handles that are well-known in the art that could be substituted for the Watson handle. A spring-clip handle is disclosed by Lindquist. This type of handle automatically applies force in the reverse direction, which provides resistance to the trigger. This would be beneficial to use on the Watson device because this handle would help prevent misfiring. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Watson handle with the Lindquist handle because the Lindquist handle would be more effective in preventing accidental actuation of the handle than the pull cord design of Watson.

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over combined Watson device as applied to claim 29 and in view of Aranyi 5483952. As mentioned above, Watson discloses only a rudimentary handle to actuate the ligation bands. Spring-based ratchet handles are well known in art. A dual spring mechanism wherein the central rod also functions as a ratchet is taught by Aranyi '952. This design is advantageous since it affords the user the benefit of using a ratchet and keeps the number of moving parts to a minimum. While it is not understood how the springs perform their function in the applicant's device since the illustrations do not show the springs, as best understood, the Aranyi handle has a first spring which is used to withdraw the serrated central rod and a second spring used to stabilize and prevent forward

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slippage of the central rod. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Aranyi handle into the combined Watson device to afford the Watson device ratcheting functionality.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4257419 A Ligature tying instrument for haemorrhoids - has pistol grip and operating trigger at opposite end to suction head with ejector connection

US 6676672 B2 Single pull wire multiple band ligator

EP 1155660 A Device for applying ligatures to haemorrhoids comprises barrel provided with grip having distal end for receiving rings, and slidable actuator

US 6610070 B1 Distal end for ligating band dispenser

WO 9965400 A Haemorrhoid treatment device for rubber band ligation suitable for first to third degree hemorrhoids


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Roberts
Paul.Roberts@uspto.gov
04/01/04



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

